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Petitions
BOX PATENT EXT.

124-420.
#37

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. SPL-53

In re: U.S. Patent No. 4,373,527

Patentee: Robert E. FISCHELL

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

REQUEST FOR *INTERIM* EXTENSION OF PATENT TERM
UNDER 35 U.S.C. § 156(d)(5)

BOX PATENT EXT.
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to Section 201(a) of the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 156(d)(5), The Johns Hopkins University ("Hopkins"), represents that it is the owner of record of United States Patent No. 4,373,527 and hereby requests an interim extension of the patent term of U.S. Patent No. 4,373,527 ("the '527 patent"). The '527 patent is due to expire on Feb. 15, 2000, and Hopkins reasonably expects that the applicable regulatory review period will extend beyond the expiration date of the '527 patent.

TIMING OF THE APPLICATION

This application is being filed during the period beginning 6 months before expiration of the '527 patent and ending 15 days before expiration of the '527 patent, as required by 37 C.F.R. § 1.790(a).

ITEMS REQUIRED BY 37 C.F.R. §§ 1.740 & 1.790

The following information is submitted in accordance with 35 U.S.C. § 156(d) and 37 C.F.R. § 1.740, and follows the format and requirements set forth in 37 C.F.R. § 1.740.

(1) "A complete identification of the ... product as by appropriate chemical and generic name, physical structure or characteristics." 37 C.F.R. §1.740(a)(1)

The product is an implantable, programmable medication infusion system now called Minimed 2007 ("MM2007"), formerly called Minimed 2001 ("MM2001"). MM2007 and MM2001 are similar mechanically, but the MM2007 contains upgraded electronic components relative to MM2001. The physical structure and characteristics of MM2007, and its predecessor MM 2001, are provided in section (9), *infra*.

(2) "A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred, " 37 C.F.R. § 1.740(a)(2).

The regulatory review period for MM2007 and MM2001 is prescribed by section 515 of the Federal Food, Drug, and Cosmetic Act.

(3) "An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred," 37 C.F.R. § 1.740(a)(3).

This provision is not applicable to an interim extension application. 37 C.F.R. § 1.790(b).

(4) "In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved," 37 C.F.R. § 1.740(a)(4).

This provision is not applicable to the present interim extension application, which relates to a medical device rather than a drug product.

(5) "A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(f) and an identification of the last day on which the application could be submitted," 37 C.F.R. § 1.740(a)(5)

This provision is not applicable to an interim extension application. 37 C.F.R. § 1.790(b).

(6) "A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration," 37 C.F.R. § 1.740(a)(6).

U.S. Patent No.	4,373,527
Inventor:	Robert E. Fischell
Issue Date:	February 15, 1983
Expiration Date:	February 15, 2000

(7) "A copy of the patent for which an extension is being sought including the entire specification (including claims) and drawings," 37 C.F.R. § 1.740(a)(7).

A copy of U.S. Patent 4,373,527 is attached as Exhibit 1.

(8) "A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or re-examination certificate issued in the patent," 37 C.F.R. § 1.740(a)(8).

U.S. Patent 4,373,527 issued on February 15, 1983, based upon an application filed on April 27, 1979. For patents which issued from applications filed prior to December 11, 1980, no maintenance fees are required. Accordingly, no maintenance fees were required for the '527 patent, and no receipts of maintenance fee payments exist.

No disclaimer has issued in connection with U.S. Patent No. 4,373,527. Copies of a Certificate of Correction issued for the '527 patent and Reexamination Certificate B1 4,373,527, issued June 27, 1995, are attached as Exhibit 2.

(9) "A statement that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product or method of using or manufacturing the approved product," 37 C.F.R. § 1.740(a)(9).

U.S. Patent No. 4,373,527 claims the device for which approval is sought, i.e., a programmable infusion system now known as MM2007 and formerly known as MM2001. MM 2007 is used to help treat diabetes mellitus, as was MM2001. MM2007 and MM2001 include three major components: (1) an implantable pump, (2) an intraperitoneal catheter, and (3) a hand-held programming device called the Personal Pump Communicator (PPC). MM 2007 and MM2001 are designed to release programmed amounts of insulin into the abdominal cavity.

Attached as Exhibit 3 is a showing which lists each applicable patent claim and demonstrates the manner in which each applicable claim reads on MM2007 and MM2001.

(10) "A statement, beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. § 156(g) in order to enable the Secretary of Health and Human Services . . . to determine the applicable regulatory review period . . . For a patent claiming a medical device . . . the effective date of the investigational device exemption (IDE) and the IDE number . . .; the date on which the application for product approval or notice of completion of a product development protocol under section 515 . . . was initially submitted and the number of the application or protocol; and the date on which the application was approved or the protocol declared to be completed" 37 C.F.R. § 1.740(a)(10)(v).

In order to enable the Secretary to determine the applicable regulatory review period, the following information is provided.

(a) The effective date of the IDE allowing implantation of MM2007 and its predecessor model (MM2001) was July 7, 1988, and the IDE number is G860065/S032.

(b) The date on which the application for product approval of MM2001 was initially submitted was August 6, 1991. The application number was P910047. This application for product approval was withdrawn shortly after its filing at the request of the FDA in view of the FDA's decision to require new studies which followed each subject for a longer period of time.

(c) As of the date of filing of this interim extension application, a new application for product approval of MM2007 has not yet been filed. Therefore, the FDA has not yet approved any application for product approval, and the FDA has not declared any protocol to be completed.

(11) "A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities" 37 C.F.R. § 1.740(a)(11).

Attached is a chronology that briefly describes the significant regulatory activities and relevant dates associated with efforts to date to obtain approval of MM2007 and MM2001 from the FDA (Exhibit 4).

(12) "A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of the extension claimed, including how the length of extension was determined," 37 C.F.R. § 1.740(a)(12).

Statement of Eligibility of the Patent for Extension

(i) It is the opinion of the applicant that U.S. Patent 4,373,527 is eligible for an extension. This opinion is based on the following information on U.S. Patent No. 4,373,527:

(a) 35 U.S.C. § 156(a) - U.S. Patent No. 4,373,527 claims the medical device for which approval is sought, a programmable infusion system now called MM2007 and formerly called MM2001).

(b) 35 U.S.C. § 156 (a)(1) - The term of the patent has not expired prior to the submission of this application, and this application is being submitted during the period beginning 6 months before expiration of the '527 patent and ending 15 days before expiration of the '527 patent.

(c) 35 U.S.C. § 156 (a)(2) - The term of said patent has never been previously extended under 35 U.S.C. § 156 (e)(1).

(d) This application for interim extension is in compliance with 37 C.F.R. §§ 1.740 and 1.790.

(e) 35 U.S.C. § 156(a)(4) - MM2007 is presently the subject of a regulatory review period as defined in 35 U.S.C. § 156(g).

(f) 35 U.S.C. § 156(d)(5) - Hopkins reasonably expects that the applicable regulatory review period will extend beyond the expiration date of the '527 patent.

(g) 35 U.S.C. § 156(c)(4) - No other patent term has been extended for the same regulatory review period for this product.

Statement as to Length of Extension Claimed

Pursuant to 37 C.F.R. §§ 1.790 and 1.791, the interim extension would extend the '527 patent from its current expiration date of February 15, 2000, for a period of up to one year or the end of the 60-day period beginning on the date on which the MM2007 receives permission for commercial marketing or use, whichever comes first.

(13) "A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to any determination of entitlement to the extension sought," 37 C.F.R. § 1.740(a)(13).

Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to any determination of entitlement to the extension sought.

(14) "The prescribed fee for receiving and acting upon the application for extension," 37 C.F.R. § 1.740(a)(14).

Pursuant to 37 C.F.R. § 1.20(j)(2), a check in the amount of $ 420.00 is enclosed with this application.

(15) "The name, address and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed," 37 C.F.R. § 1.740(a)(15).

Please direct all inquires and correspondence relating to this application for patent term extension to:

Francis A. Cooch
Office of Patent Counsel
Johns Hopkins University
Applied Physics Laboratory
11100 Johns Hopkins Road
Laurel, MD 20723-6099

(16) "A duplicate of the application papers, certified as such," 37 C.F.R. § 1.740(a)(16).

Enclosed is a certification that this application for patent extension, including its attachments, is being submitted as one original and one duplicate copy thereof (Exhibit 5).

(17) "An oath or Declaration as set forth in 37 C.F.R. § 1.740(b)," 37 C.F.R. § 1.740(a)(ii).

The requisite declaration pursuant to 37 C.F.R. § 1.740(b) is attached as Exhibit 6.

Respectfully submitted,

January 28, 2000
Date

Francis A. Cooch
Francis A. Cooch
Reg. No. 31,495

Office of Patent Counsel
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Applied Physics Laboratory
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JHU/APL Docket No. SPL-53

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EXPRESS MAIL CERTIFICATE

"Express Mail" label number EG124451210US

Date of Deposit: January 28, 2000

I hereby certify that the following attached papers relating to the patent identified above consisting of the following:

1. Postcard receipt
2. Check for $420.00
3. Request for Interim Extension of Patent Term with six exhibits (in duplicate) as follows: Request (10 pages), Ex. 1 - copy of 4,373,527; Ex. 2 - copies of Cert. of Corr. and Reexam Cert.; Ex. 3 - list of applicable claims; Ex. 4 - chronology of activities; Ex. 5 - certification; and Ext. 6 - declaration.

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

Francis A. Cooch

Francis A. Cooch